



INSTITUTE OF MEDICINE

SM00137, Patient access and health economics of ATMPs (Advanced Therapy Medicinal Products), 1.5 credits

Tillgängliggörande och hälsoekonomiska aspekter på ATMPs (Advanced Therapy Medicinal Products), 1,5 högskolepoäng

Third-cycle level / Forskarnivå

Confirmation

This syllabus was confirmed by the Council for PhD Education at Sahlgrenska Academy on 2024-02-23, and is valid from Autumn semester 2024.

Responsible Department

Institute of Medicine, Sahlgrenska Academy

Entry requirements

Registered PhD-student or PhD-degree in relevant subject. PhD-students from National Research School of ATMP are given priority to admission. We welcome participants from all Swedish and international universities that are involved in research activities related to ATMP.

Learning outcomes

The aim of this course is to give students a basic understanding of health economic considerations of ATMPs (advanced therapy medicinal products). The focus is on methods for economic evaluation and health technology assessment (HTA) and patient access requirements in Sweden. With the acquired knowledge and skills, the students will be able to describe and discuss reimbursement processes and patient access considerations for ATMPs, and to contribute to the planning and implementation of economic evaluations and HTAs for ATMPs.

Knowledge and understanding

- Describe concepts and methods of health economics and HTA (health technology assessment)
- Identify key components of health economic evaluations and HTAs required for ATMPs

- Critically discuss requirements for reimbursement and patient access to ATMPs

Competence and skills

- Identify and assess relevant methods, models, and concepts within economic evaluations and HTAs of relevance for ATMPs
- Actively contribute to planning the design of economic evidence generation studies for ATMPs

Judgement and approach

- Problematize requirements for sound decision-making on ATMPs from diverse perspectives including healthcare system, healthcare professionals, patients, sustainability, and society

Course content

The course forms a theoretical and methodological foundation for understanding and exploring patient access and reimbursement issues within ATMPs. The methods for economic evaluation and health technology assessment, in general as well as particularities for ATMPs, are described in lectures and guest lectures, while the application of the methods for ATMPs are discussed in group-based exercises and seminar. Guest lecturers with expertise in patient access aspects of ATMPs discuss their experiences and perspectives in a panel discussion. Reimbursement policy and patient access lectures focus on current Swedish circumstances, with an international perspective reflected in group discussions. An individual assignment describing the design of a HTA study of a selected ATMP product is presented and discussed in an examination seminar.

Types of instruction

The course includes lectures, guest lectures, a guest lecturer panel discussion, group and individual work, and seminars, both campus- and distance-based.

Language of instruction

The course is given in English

Grades

The grade Pass (G) or Fail (U) is given in this course.

Types of assessment

An individual assignment presented and discussed in an examination seminar.

Course evaluation

The course evaluation will be provided both as a written questionnaire (joint for Sahlgrenska

Academy) and orally as a discussion between the students and the course leader(s). The course responsible teacher compiles analysis of the course evaluation and makes suggestions for further development of the course. The result and any changes in the set-up of the course shall be communicated both to the students that carried out the evaluation and to the students who are about to start the course.